

### REMARKS

Claims 1-66 were pending in the application. As the restriction requirement imposed in Paper 8 has been made final, claims 1-13 and 38-66 have been withdrawn from consideration, and are canceled by the present amendment, as they are drawn to non-elected subject matter. Claims 14-37 have been rejected. By the present amendment, claims 14-37 have been canceled, and new claims 67-83 have been added.

Claims 26, 29, 31 and 32 were rejected under 35 U.S.C. Section 101 as being directed to non-statutory subject matter. The Examiner indicated that this rejection can be overcome by indicating that the nucleic acids are isolated. New claims 76-83 recite "an isolated nucleic acid." Therefore, this rejection does not apply to new claims 76-83.

Claims 15, 16, 17 and 28 were rejected under 35 U.S.C. Section 112, second paragraph as being indefinite. The Office Action provided no discussion or explanation for the basis of this rejection, making it impossible for Applicants to respond. In any event, the claims subject to this rejection have been cancelled, rendering it moot. Claims 35 and 36 were rejected for the recitation of "said vector", which lacked antecedent basis. These claims have been cancelled, making this rejection moot.

Claims 25 and 37 were rejected under 35 U.S.C. Section 112, first paragraph for lack of enablement. The Office Action states that the Applicants have not provided guidance in the specification as to how to make the synthetic promoter G1090, nor made a deposit of the vector. Although claims 25 and 37 have been canceled, new claim 74 recites the G1090 promoter. Applicants respectfully submit that this rejection should not apply to claims 25 and 37, and does not apply to new claim 74. The specification at page 19, lines 26-28 describes the construction of the G1090 promoter in sufficient detail to enable a person of ordinary skill in the art to reproduce it. The specification states that the G1090 promoter consists of four copies of a G-box, with a specified nucleic acid sequence, fused to the -90 35S promoter, a promoter the sequence of which is well known in the art, and is widely available. The techniques required to create the promoter are nothing more than the routine molecular techniques well known in the art for gene splicing and nucleic acid synthesis. The Examiner may

be of the unstated opinion that the specification is not clear as to whether the four copies of a G-box should be fused to the 5' or to the 3' and of the 35S promoter. However, transcription enhancers such as the G-box are known in the art to function when positioned at the 5' end of a promoter and it would be assumed by a person of ordinary skill in the art that the enhancers are placed in that position. Even if, for the sake of argument, one were to assume that a person of ordinary skill in the art would not know at which end of the promoter to place the enhancers, there are only two possible configurations, and it is well within the abilities of the person of ordinary skill in the art to determine the proper configuration using routine techniques. Applicants therefore submit that this rejection is unwarranted, and respectfully request that it be withdrawn.

Claims 14-24 and 26-36 have been rejected under 35 U.S.C. Section 102(e) as being anticipated by Goff et al. The Office Action states that Goff et al. teach vectors and isolated nucleic acids comprising a chemically inducible promoter, and further comprising a regulatory domain of a glucocorticoid and/or an estrogen receptor, a selectable marker such as an antibiotic or an herbicide resistant gene, a CaMV 35S promoter, the DNA-binding domain and upstream activating region of GAL4, DNA encoding the VP16 transactivating domain, the DNA binding domain of the LexA repressor, nucleic acids encoding luciferase and a gene of interest. Office Action at 5.

In order to anticipate a claim, a prior art reference must contain every element of the claimed invention, arranged as in the claim under review. C.R. Bard Inc. v. M3 Systems Inc., 48 USPQ 2d 1225, 1230 (Fed. Cir. 1998). New claims 67 and 76, and claim 77 by reference to claim 76, recite specific elements arranged in a specific manner. Claims depending therefrom necessarily incorporate these same elements. Goff does not teach the selection of these specific elements from among all of the various elements disclosed in that reference, nor does Goff teach that these elements, or functional equivalents of these elements, should or could be arranged in the particular manner recited in the claim.

Goff teaches a "heterodimeric" control system, where two different receptor polypeptides together activate gene transcription. Col. 2, lines 55-65; Figures 1-3. When identical receptor polypeptides are used in the Goff system, to form a "homodimer," the result is gene repression, not activation. Col. 10, lines 13-48. The present invention,


directed to a homodimeric system that achieved tight control of gene activation is completely at odds with the teachings of Goff. With the system of the present claims, 100-200 fold induction of transcription is routinely achieved. See Examples 12 and 13. Goff, on the other hand, specifically states that Class I receptor polypeptides, such as the estrogen receptor recited in the present claims, do not function to activate gene expression. Col. 1, line 60 - col. 2, line 12. Thus, the subject matter of the present claims is not taught in Goff.

The United States Court of Appeals for the Federal Circuit addressed a similar situation in Ecolochem, Inc., v. Southern California Edison, 56 U.S.P.Q.2d 1065 (Fed. Cir. 2000). The invention in Ecolochem related to methods of deoxygenating water or other liquids with hydrazine by passing a liquid-hydrazine mixture through activated carbon, thus catalyzing a reaction between hydrazine and the oxygen dissolved in the liquid, followed by passing the mixture through a strong cation exchange resin and a strong anion exchange resin to remove contaminants and unreacted hydrazine. 56 U.S.P.Q.2d at 1067. The defendant asserted that the claims in suit were anticipated by either of two references, which disclosed various methods for deoxygenation of water, including by palladium/hydrogen in combination with a mixed bed column (having both cation and anion exchange resins), and by hydrazine over a carbon catalyst bed. 56 U.S.P.Q.2d at 1070. The Federal Circuit held that the cited references could not anticipate the claims, even though they disclose each element thereof at various parts of the reference, because they did not disclose every element of the claims arranged in the recited manner (i.e., did not disclose the use of hydrazine/carbon followed by an ion exchange resin). 56 U.S.P.Q.2d at 1070-1071. The Ecolochem case is directly applicable in the present case, where the asserted art merely discloses at various points the separate elements of the claim, without relating them one to the other or arranging them in the manner specified in the claims.

Goff does not disclose every element of the claimed invention, arranged as in the claims. Applicants respectfully submit that the Goff reference therefore cannot anticipate the new claims 67-83.

**CONCLUSION**

Applicants submit that new claims 67-83 are in condition for allowance, and earnestly solicit favorable action thereon.

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**Marked-up Copy of Amended Claims**

67. (new) A vector comprising a DNA sequence encoding a transcription factor, having the following elements in the 5' to 3' direction, i) a promoter, ii) DNA encoding a DNA binding domain of the bacterial repressor LexA, iii) DNA encoding a transactivating domain of VP16, iv) DNA encoding the regulatory domain of an estrogen receptor.
68. (new) The vector of claim 67 wherein said vector further comprises a gene encoding a selectable marker or a screenable marker, the expression of which is controlled by the transcription factor.
69. (new) The vector of claim 68 wherein said gene is *ipt*, *CK11*, *luciferase*, a member of the *knotted* family, a gene the expression of which can promote shoot regeneration and development, or a gene the expression of which promotes somatic embryogenesis.
70. (new) The vector of claim 67 wherein said vector further comprises one or more genes of interest.
71. (new) The vector of claim 68 wherein said gene is a gene for antibiotic resistance.
72. (new) The vector of claim 68 wherein said gene is a gene for herbicide resistance.
73. (new) The vector of claim 67, further comprising a luciferase gene or a gene that causes anthocyanin production.
74. (new) The vector of claim 73, wherein the gene that causes anthocyanin production is the maize *Lc* gene.

75. (new) The vector of claim 67 wherein said promoter is a constitutive promoter.
76. (new) The vector of claim 75 wherein said constitutive promoter is G1090.
77. (new) The vector of claim 67 wherein said promoter is a tissue-specific promoter.
78. (new) An isolated nucleic acid encoding a transcription factor, comprising, in the 5' to 3' direction, i) a constitutive promoter, ii) DNA encoding a DNA binding domain of bacterial repressor LexA, iii) DNA encoding a transactivating domain of VP16, iv) DNA encoding a regulatory domain of an estrogen receptor.
79. (new) A transgenic plant or transgenic plant cell comprising a nucleic acid of claim 78.
80. (new) The transgenic plant or transgenic plant cell of claim 79, further comprising a gene encoding a selectable marker or a screenable marker the expression of which is controlled by the transcription factor.
81. (new) The transgenic plant or transgenic plant cell of claim 80, wherein the gene is selected from the group consisting of *ipt*, *CKI1*, a member of the *knotted* family, a gene the expression of which can promote shoot regeneration and development, or a gene the expression of which promotes somatic embryogenesis.
82. (new) The transgenic plant or transgenic plant cell of claim 79, further comprising a luciferase gene or a gene that causes anthocyanin production.
83. (new) The transgenic plant or transgenic plant cell of claim 82, wherein the gene that causes anthocyanin production is the maize *Lc* gene.